



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/630,320	07/30/2003	Shalaby W. Shalaby	SHA-26-DIV2	8741

29698 7590 10/11/2005

LEIGH P. GREGORY
ATTORNEY AT LAW
PO BOX 168
CLEMSON, SC 29633-0168

EXAMINER

HAMPTON HIGHTOWER, PATRICIA

ART UNIT	PAPER NUMBER
----------	--------------

1711

DATE MAILED: 10/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/630,320

Applicant(s)

SHALABY ET AL.

Examiner

Patricia Hightower

Art Unit

1711

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 7/30/2003 & 7/18/2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) 1-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 11/10/2003.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Response to Amendment

The preliminary amendments filed July 30, 2003 and July 18, 2005 are acknowledged; claims 1-24 are presently pending; claims 1-17 have been withdrawn from consideration in the preliminary amendment filed July 30, 2003; claims 18-24 will receive an office action on the merits.

Information Disclosure Statement

The information disclosure statement filed November 10, 2003 has been considered and has been made of record.

In view of the papers filed July 30, 2003, the inventorship in this nonprovisional application has been changed by the deletion of ***Dan Akerfeldt, Fredrick Preiniz and Per Egnelov***.

The application will be forwarded to the Office of Initial Patent Examination (OIPE) for issuance of a corrected filing receipt, and correction of Office records to reflect the inventorship as corrected.

Obviousness-type Double Patenting Rejection

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Art Unit: 1711

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 18-24 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-24 of U.S. Patent No. 6,794,485. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant application and USP 6,794,485 are viewed as claiming overlapping subject matter. The instant application claims a composite tubular cover or mantle for a stent comprising a polymeric matrix reinforced with monofilament cross-spirals, wherein at least one of the matrix and the reinforcement comprise an absorbable, crystalline, monocentric, polyaxial copolymer having at least three axes originating and extending outwardly from the central atom, each axis comprises an amorphous, flexible component adjacent to and originating from the central atom, derived from a cyclic monomer selected from carbonates and lactones and a rigid, crystallizable component extending outwardly from the amorphous, flexible compone comprising repeat units derived from at least one lactone (i.e., caprolactone, p-dioxanone, 1,5-dioxepan-2-one and trimethylene carbonate, wherein the copolymer has a melting temperature greater than 120°C, a heat of fusion greater than 10 J/g and an endothermic transition at 40 – 100°C which can be controlled by subsequent heat treatment of the copolymer.

The patent claims an absorbable, crystalline, monocentric, polyaxial copolymer comprising three axes originating and extending outwardly from the center of the copolymer, each axis comprising an amorphous, flexible component and a rigid

Art Unit: 1711

crystallizable component and a composite tubular cover or mantle for a stent comprising a polymerix matrix reinforced with monofilament cross-spirals, wherein at least one of the matrix is micropous; although the patent is silent as to the claimed properties or characteristics of the copolymer and teaching the heat treatment as instantly claimed. Silence does not preclude the patent's copolymer from possessing said characteristics or properties since both of the copolymer on the face appear to be the same or similar.

Applicant is reminded that it is permissible to use the specification to define what appears in the claims and at col. 11, Example 10, the patentee clearly discloses a general method for assembling composite stent mantle. Thus, the instant application is viewed as being an obvious variation of the patent's invention.

Prior Art

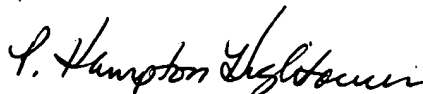
The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. These references are cited to show the state of the art of crystalline copolymers and medical devices prepared therefrom; Shalaby, Bezwada, and Tang.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia Hightower whose telephone number is (571) 272-1073. The examiner can normally be reached on M-F from 9:30 A.M. - 6:00 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Seidleck can be reached on (571) 272-1078. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1711

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


P. Hampton Hightower
Primary Examiner
Art Unit 1711

P. Hightower:ph
September 30, 2005